

Legend: (Proposed New Rule)

Regular Print = Proposed new language

§157.133 Requirements for Stroke Facility Designation

(a) The Office of Emergency Medical Services (EMS)/Trauma Systems Coordination (office) shall recommend to the Commissioner of the Department of State Health Services (commissioner) the designation of an applicant/healthcare facility (facility) as a stroke facility at the level(s) for each location of a facility the office deems appropriate.

(b) Comprehensive Stroke Facility designation, Level I--The facility, including a free-standing children's facility, meets the current Brain Attack Coalition essential criteria for an accredited comprehensive stroke center; actively participates on the appropriate Regional Advisory Council (RAC); and submits data to the Texas Department of State Health Services (DSHS) as requested.

(c) Primary Stroke Facility designation, Level II--The facility, including a free-standing children's facility, meets the current Brain Attack Coalition essential criteria for an accredited primary stroke center; actively participates on the appropriate Regional Advisory Council (RAC); and submits data to the Texas Department of State Health Services (DSHS) as requested.

(d) Support Stroke Facility designation, Level III--The facility, including a free-standing children's facility, meets essential criteria for an accredited primary stroke center in association with a primary or comprehensive stroke facility; actively participates on the appropriate Regional Advisory Council (RAC); and submits data to the Texas Department of State Health Services (DSHS) as requested.

(e) A healthcare facility is defined under these rules as a single location where inpatients receive hospital services or each location if there are multiple buildings where inpatients receive hospital services and are covered under a single hospital license. Each location shall be considered separately for designation.

(f) The designation process shall consist of three phases.

(1) First phase. The application phase begins with submitting to the office a timely and sufficient application for designation as a stroke facility and ends when the survey report is received by the office.

(2) Second phase. The review phase begins with the office's review of the survey report and ends with its recommendation to the commissioner whether or not to designate the facility. This phase also includes an appeal procedure governed by the department's rules for a contested case hearing and by Government Code, Chapter 2001.

(3) Third phase. The final phase begins with the commissioner reviewing the recommendation and ends with his/her final decision.

(e) If the commissioner concurs with the recommendation to designate, the facility shall receive a letter and a certificate of designation valid for two years.

(f) It shall be necessary to repeat the stroke designation process as described in this section prior to expiration of a facility's designation or the designation expires.

(g) A designated stroke facility shall:

(1) comply with the provisions within these sections; all current state and system standards as described in this chapter; and all policies, protocols, and procedures as set forth in the system plan;

(2) continue its commitment to provide the resources, personnel, equipment, and response as required by its designation level;

(h) For a facility seeking initial designation, a timely and sufficient application shall include:

(1) the department's current "Complete Application" form for the appropriate level, with all fields correctly and legibly filled-in and all requested documents attached, hand-delivered or sent by postal services to the office;

(2) full payment of the \$100 designation fee enclosed with the submitted "Complete Application" form;

(3) any subsequent documents submitted by the date requested by the office;

(4) a stroke designation survey completed within one year of the date of the receipt of the application by the office; and

(5) a complete survey report, including patient care reviews, that is within 180 days of the date of the survey and is hand-delivered or sent by postal services to the office.

(i) If a hospital seeking initial designation fails to meet the requirements in subsection (h)(1) - (5) of this section, the application shall be denied.

(j) For a facility seeking re-designation, a timely and sufficient application shall include:

(1) the department's current "Complete Application" form for the appropriate level, with all fields correctly and legibly filled-in and all requested documents attached, hand-delivered or sent by postal services to the office one year or greater from the designation expiration date;

(2) full payment of the \$100 designation fee enclosed with the submitted "Complete Application" form;

(3) any subsequent documents submitted by the date requested by the office; and

(4) a complete survey report, including patient care reviews, that is within 180 days of the date of the survey and is hand-delivered or sent by postal services to the office no less than 60 days prior to the designation expiration date.

(k) If a healthcare facility seeking re-designation fails to meet the requirements outlined in subsection (j)(1) - (4) of this section, the original designation will expire on its expiration date.

(l) The office's analysis of the submitted "Complete Application" form may result in recommendations for corrective action when deficiencies are noted and shall also include a review of:

(1) evidence of current participation in RAC/regional system planning; and

(2) the completeness and appropriateness of the application materials submitted, including the submission of a non-refundable application fee of \$100.00.

(m) A RAC should develop a stroke system plan based on standard guidelines for comprehensive system development. The stroke system plan is subject to approval by DSHS.

(n) DSHS may review the plan to assure that:

(1) all counties within the TSA have been included unless a specific county, or portion thereof, has been aligned within an adjacent system;

(2) all health care entities and interested specialty centers have been given an opportunity to participate in the planning process; and

(3) the following components have been addressed:

(A) stroke prevention;

(B) access to the system;

(C) communications;

(D) medical oversight;

(E) pre-hospital triage criteria;

(F) diversion policies;

(G) bypass protocols; (15 minute to the highest level facility)

(H) regional medical control;

(I) regional stroke treatment guidelines;

(i) Guidelines consistent with current standards shall be developed, implemented, and evaluated.

(ii) Individual agencies and medical directors may, and are encouraged, to exceed the minimum standards.

(iii) Stroke patients will be cared for by health professionals with documented education and skill in the assessment and care of stroke throughout their pre-hospital and hospital course.

(iv) Stroke patients will have their medical care, as documented by pre-hospital run forms and hospital charts, reviewed by the individual entity's medical director for appropriateness and quality of care.

(v) Stroke patients will have deviations from standard of care addressed through a documented stroke performance improvement process.

(J) facility triage criteria;

(K) inter-hospital transfers;

(L) planning for the designation of stroke facilities, including the identification of the comprehensive, primary, and support stroke facility(ies); and

(M) a performance improvement program that evaluates processes and outcomes from a system perspective.

(o) DSHS approval of the completed plan may qualify health care entities participating in the system to receive state funding for stroke care if funding is available.

(p) A healthcare facility may not use the terms "stroke facility", "stroke hospital", "stroke center", "comprehensive stroke center", "primary stroke center", "support stroke facility" or similar terminology in its signs or advertisements or in the printed materials and information it provides to the public unless the healthcare facility is currently designated as that level of stroke facility according to the process described in this section.

(q) If the hospital or center loses its designation, no further public advertising is allowed and existing advertising must, where feasible, be removed from public distribution within 60 days from the date of removal. To the extent that removal of advertisement is infeasible, for example advertisement previously distributed in magazines, newspapers or on the

internet, any automatic renewal of such advertisement shall be cancelled upon removal, and no further advertisement in said media shall be pursued.

(r) The office may review, inspect, evaluate, and audit all stroke patient records, stroke performance improvement, committee minutes, and other documents relevant to stroke care in any designated stroke facility or applicant/healthcare facility at any time to verify compliance with the statute and this rule, including the designation criteria.

(s) National averages and percentages based on yearly surveys of centers outcome and quality improvement plan submitted in the certification process may be used to trigger audits.

(t) Designated stroke facilities failing to meet essential criteria of certification shall notify the office; its RAC plus other affected RACs, EMS providers, and the healthcare facilities to which it customarily transfers-out stroke patients or from which it customarily receives stroke transfers-in, if it no longer provides stroke services commensurate with its designation level.

(A) Essential criteria that are critical include such things as:

- (i) neurosurgery capabilities (Level I);
- (ii) neurointerventional surgery capabilities (Level I);
- (iii) neurology capabilities (Level I, II);
- (iv) anesthesiology (Levels I);
- (v) emergency physicians (all levels);
- (vi) stroke medical director (all levels);
- (vii) stroke nurse coordinator/program manager (all levels); and
- (viii) stroke registry (all levels).

(B) If the facility chooses to apply for a lower level of stroke designation, it may do so at any time; however, it may be necessary to repeat the designation process. There shall be a paper review by the office to determine if and when a full survey shall be required.

(C) If the facility chooses to relinquish or change its stroke designation, it shall provide at least 30 days notice to the RAC and the office.